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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,164	10/11/2005	Leah Tolosa	UMBC-0012	2038
68733	7590	05/20/2009	EXAMINER	
Rene A. Vazquez			SHEN, BIN	
P.O. Box 9744				
McLean, VA 22102			ART UNIT	PAPER NUMBER
			1657	
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			05/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,164	TOLOSA ET AL.	
	Examiner	Art Unit	
	BIN SHEN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 22-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-11, 14-21, 42 and 43 is/are rejected.
- 7) ☒ Claim(s) 8,9, 12, 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The IDS received 10/11/2005, the preliminary amendment received 10/11/2005 have been entered.

Election

Applicant's election with traverse of Group I, claims 1-21, 42, 43, election of species glutamine-binding protein for species C in the reply filed on 2/27/2009 is acknowledged. During a telephone conversation with Mr. Vazquez on March 24, 2009, a provisional election of species for naturally occurring sugar for type A and glucose for type B was made with traverse to prosecute the elected invention. The traversal is on the ground(s) that there is no serious burden to search the entire application. This is not found persuasive because the product/protein search and the method search are not coextensive and are conducted in different data bases as stated in the previous requirement for restriction.

The requirement is still deemed proper and is therefore made FINAL.

Claims 22-41 are nonelected and thus are withdrawn from further consideration.

Only claims 1-21, 42, 43 are presented for examination on the merits.

Benefit of priority is May 9, 2003.

Specification

The use of the trademark "GlutaMAX" on page 60, has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification is objected to for inappropriate notation of an internet address. On page 67, line 8, an internet address is cited in an unacceptable form. See MPEP § 707.05(e) for the acceptable notation of an internet address.

Claim Objections

Claims 8, 9, 12, 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 42, 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantial change" in claims 1, 42, on line 5 is a relative term which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear if "substantial change" means the same kind of change (such as color change vs. electron change etc.) and what level of change qualifies for "substantial change".

Since the Examiner can not determine the scope of the invention (such as how much change is substantial change when the protein sensing molecule is bound to the analyte) due to the use of the term “substantial change”, the following art rejections applied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10, 11, 14-21, 42, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowicz (USPN 6197534).

Lakowicz teaches a glucose/galactose binding protein (GGBP) for determining the concentration of glucoses (col. 4, lines 21-24) comprising GGBP with two sets of different fluorescent labels: 1st set of labels including aniline-naphthalene sulfonate and green fluorescent protein (col. 9, lines 24-27, Fig. 16); 2nd set of labels including blue fluorescent protein at the N-terminal and green fluorescent protein at the C-terminal (col. 3, lines 46-49, and Fig. 18) which are labeled at the double-cysteine mutant GGBP glucose sensors (col. 7, Example 3) labels (detectable quality), a radiation source with an excitation wavelength of 325 nm is used (col. 10, line 62), and a spectrofluorometer is used as means for detecting emission spectra (col. 10, lines 59-61) 47.

Therefore Lakowicz teaches a protein sensing molecule (**Claim 1**) (glucose/galactose binding protein-[Claim 19]: col. 4, lines 21-24) with two sets of different fluorescent labels (**Claim 4**): the first set of the labels including aniline naphthalene-6-sulfonic acid (labeled at a single cysteine mutation at position 26, **Claim 20**) which is a polarity-sensitive fluorophore label (col. 7, lines 39-41, and Fig. 16, **Claims 2, 5, 6**) and a green fluorescent protein which is a fluorophore label (**Claims 3 & 7**); the second set of the labels including the blue fluorescent protein which is attached at the N-terminal of GGBP (Fig. 18, **Claim 10**), the green fluorescent protein which is attached at the C-terminal of the protein, shown in Fig. 16 (**Claim 11**), the

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analyte comprise naturally occurring sugar such as glucose/galactose (**Claims 14 & 15**) (for glucose detection, See col. 4, lines 3), the GGBP may be labeled with a single fluorophore and used as a glucose sensor in which the conformational twist of the protein induced by the binding of glucose causes a change (col. 7, lines 27-32) in the environment around the fluorophore (read as cause the first detectable quality to be shielded/unshielded, **Claims 16 & 17**), the GGBP has glucose/galactose binding site (**Claim 18**) (Fig. 1), the GGBP protein sensor is modified by substituting at one cysteine residue is shown in Fig. 16 (**Claim 20**), the GGBP protein sensor is modified by substituting two cysteine residues in Fig. 18 (**Claim 21**), a radiation source with an excitation wavelength of 325 nm is used (col. 10, line 62) (**Claim 42**), and a spectrofluorometer is used as means for detecting emission spectra (col. 10, lines 59-61) (**Claim 43**).

Claims 1-6, 14-18, 20, 42, 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kella (1984).

Kella teaches a dual labeled lectin molecule (abstract) that inherently binds to carbohydrate (such as galactose, see page 4777, right column, 2nd paragraph, lines 1- 5). The lectin is labeled with donor (ANS: binding to the hydrophobic site of lectin (page 4778, right column, 4th full paragraph) and acceptor molecule (MNP or DABMI, covalently attached to the thiol group-read as cysteine at the putative carbohydrate binding site of lectin) (page 4778, right column, 4th full paragraph, lines 13-15, also see page 4778, left column, 4th full paragraph, line 4). Kella also teaches radiation of the sample and detection of the emission of the labeled lectin molecule (page 4778, left column, 8th full paragraph).

Comment [K1]: you haven't addressed this comment

Therefore, Kella teaches labeled lectin molecule (**Claims 1-4**) as a protein sensing molecule with two different labels: 1-anilino-8-naphthalenesulfonate (ANS) as fluorophore label (**Claims 5 & 6**, see page 4778, right column, 4th full paragraph) and a mercurial and/or maleimide as acceptor labels (MNP or DABMI, page 4777, end of right column), the lectin molecule inherently binds to sugar such as galactose (the lectin also named LBL-III or D-GalNAc-binding glycoprotein) because it have carbohydrate binding sites (page 4777, left column, 2nd paragraph, **Claims 14 , 15, 18**), binding of the analyte inherently shield/unshield the detectable quality for the fluorescence energy transfer to measure fluorescence by the spectrofluorometer (page 4778, left column, 8th full paragraph, **Claims 16 & 17**), one of the label

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(DABMI) is incorporated into the protein sensor molecule through cysteine (thiol group, page 4778, left column, 4th full paragraph, **Claim 20**), the samples were radiated at 350 or 400 nm and emission was recorded (page 4778, left column, 8th full paragraph, **Claims 42 & 43**).

Conclusion

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen

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/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656